

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	Group Art Unit: not yet assigned
Deborah Ann Ansaldi et al.	Examiner: not yet assigned
Serial No.: not yet assigned	
Filed: August 15, 2003	CUSTOMER NO: 09157
For: SEPARATION OF POLYPEPTIDE MONOMERS	Express Mail Label No. EV 351 927 980 US Date Mailed: August 15, 2003

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

☒ **37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

☐ **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set

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forth in 37 CFR § 1.17(p) or a statement as specified in 37 CFR § 1.97(e), as checked below.

☐ **37 CFR § 1.97(d)**

- after the period specified in CFR § 1.97(c), and is accompanied by the fee set forth in 37 CFR § 1.17(p) **and** a statement as specified in 37 CFR § 1.97(e), as checked below.

[If either of boxes 37 CFR § 1.97(c) or 37 CFR § 1.97(d) is checked above, the following statement under 37 CFR § 1.97(e) may need to be completed.]

- ☐ **37 CFR § 1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR § 1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR § 1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR § 1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR § 1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

**Those patent(s) or publication(s) which are marked with an asterisk (\*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. 09/320,100, filed May 26, 1999 and relied upon in this application for an earlier filing date under 35 USC § 120.**

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A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) [Required]

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR § 1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.


In accordance with 37 CFR § 1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630.

Respectfully submitted,

GENENTECH, INC.

Date: August 15, 2003

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FORM PTO-1449  <b>LIST OF DISCLOSURES CITED BY APPLICANT</b> (Use several sheets if necessary)		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P1363R1C1	Serial No. not yet assigned		
				Applicant Ansaldi et al.			
				Filing Date 15 Aug 2003			
U.S. PATENT DOCUMENTS							
Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	* 1	09/304,465		Basey et al.			03.05.99
	* 2	4,228,154	14.10.80	Fisher et al.			
	* 3	4,764,279	16.08.88	Tayot et al.			
	* 4	4,765,903	23.08.88	D'Andrea et al.			
	* 5	5,110,913	05.05.92	Coan et al.			
	* 6	5,231,178	27.07.93	Holtz et al.			
	* 7	5,250,663	05.10.93	Tenold, R.			
	* 8	5,256,294	26.10.93	Van Reis, R.			
	* 9	5,490,937	13.02.96	Van Reis, R.			
FOREIGN PATENT DOCUMENTS							
Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No
	*10	452,753	23.10.91	EPO			
	*11	460,426 B1	17.09.97	EPO			
	*12	7,285,885	31.10.95	JAPAN (ABSTRACT ONLY)			
	*13	WO 92/04970	02.04.92	PCT			
	*14	WO 99/57134	11.11.99	PCT			
	*15	96/40776	19.12.96	WO			
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)							
	*16	Arndt, K. M., et al., "Factors Influencing the Dimer to Monomer Transition of an Antibody Single-Chain Fv Fragment" <u>Biochemistry</u> 37:12918-12926 (1998)					
	*17	Chang et al., "Single-Step Solubilization and Folding of IGF-1 Aggregates from Escherichia coli" <u>Protein Folding: In Vivo and In Vitro</u> , American Chemical Society, Chapter 14, pps. 178-188 (1993)					
	*18	Chaudhary, V. K., et al., "A recombinant immunotoxin consisting of two antibody variable domains fused to Pseudomonas exotoxin" <u>Nature</u> 339:394-397 (Jun 1, 1989)					
	*19	Elliott et al., "Yeast-Derived Recombinant Human Insulin-Like Growth Factor I: Production, Purification, and Structural Characterization" <u>J. Protein Chem.</u> 9(1):95-104 (1990)					
	*20	Hahn et al., "Bovine whey fractionation based on cation-exchange chromatography" <u>J. of Chromatography</u> 795:277-287 (Feb 1998)					
	*21	Harlow et al., "Antibody Molecules" <u>Antibodies: A Laboratory Manual</u> , Cold Spring Harbor Laboratory pps. 7, 10 (1988)					
	*22	Jiskoot, W., et al., "Two-step purification of a murine monoclonal antibody intended for therapeutic application in man - Optimisation of purification conditions and scaling up" <u>J. of Immunological Methods</u> 124:143-156 (1989)					
	*23	Lemque et al., "Study of the adsorption of self-associating proteins on an anion exchanger: Application to the chromatography of $\beta$ -lactoglobulin B" <u>Journal of Chromatography</u> 599:255-265 (1992)					
	*24	Lynch, Paul, et al., "System for Aggregate Removal from Affinity-Purified Therapeutic-Grade Antibody" <u>Genetic Engineering News</u> 17(19):17 (Nov 1, 1997)					
Examiner					Date Considered		
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

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				Applicant Ansaldi et al.	
				Filing Date 15 Aug 2003	Group not yet assigned
<b>OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)</b>					
	*25	Roitt, "Molecules Which Recognize Antigen" <u>Essential Immunology</u> , Sixth edition, Blackwell Scientific Publications pps. 31, 40 (1988)			
	*26	Yang et al., "Influence of column type and chromatographic conditions on the ion exchange chromatography of immunoglobulins" <u>J. of Chromatography</u> 743:171-180 (1996)			
	*27	Yang, J., et al., "A Genetically Engineered Single-Chain FV/TNF Molecule Possesses the Anti-Tumor Immunoreactivity of FV as well as the Cytotoxic Activity of Tumor Necrosis Factor" <u>Molecular Immunology</u> 32(12):873-881 (1995)			
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*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					